

### **REMARKS**

This paper is filed in response to the Office Action, mailed August 03, 2006. A response to the Office Action was due on November 03, 2006. Applicant is filing this response with a three-month extension of time, therefore, this response, filed on or before February 3, 2007, is to be considered timely.

Claims 1, 2 and 4-25 are pending in the application. Claims 1, 2, and 4-25 have been rejected. No new subject matter has been added to the subject application with the filing of this amendment. Applicants reserve their right to file continuation applications on the subject matter from the canceled claims.

### **Rejection under 35 U.S.C. §112, First Paragraph**

The Examiner maintained that claims 1-26 were rejected under §112, first paragraph, because the specification, while being enabling for the treatment of neuroblastoma, glioblastoma and rhabdomyosarcoma, does not reasonably provide enablement for the treatment of all types cancer using the claimed compounds. Applicant respectfully traverses this rejection and provides the following comments.

In response, applicant believes that the claims are adequately enabled by the original disclosure. The Examiner has the initial burden to establish a reasonable basis to question enablement. See MPEP 2164.04. Contrary to the Examiner's position, applicant respectfully suggests that he has adequately shown a sufficient number of embodiments to reasonably represent what is being claimed.

In this case, applicant has presented numerous examples of certain cancers in their specification. The specification specifically asserts that the inventive treatment is useful for treating "cancers," "cancer" and a "variety of cancers". See Instant Specification, page 1, line 1; page 2, line 20, page 3, lines 11-19; and page 7, lines 26 to page 10, line 23. The Examiner has even pointed out how one of skill in the art would recognize that Friedman teaches a method of treating cancer (gliomas, melanomas, carcinomas, sarcoma, leukemia, etc.) by use of temozolomide. Col. 10, Lines 35-65

Applicant respectfully suggests that the disclosure in the specification "reasonably correlates" to the scope of the claims. The examples in the Specification do not limit what is covered by the claims. The claims to which the

Examiner objects are not broader than the disclosure and one skilled in the art can make and use the claimed invention without undue examination. Therefore, the claimed subject matter is fully enabled.

Applicant reiterates his previous statement that per the first page of applicants specification and the Examiner's own references, that the claimed compounds have an effect on a number of cancers. Burton shows the anti-tumor effect of tumor DNA of irinotecan (see Burton, page 3, middle two paragraphs). Applicant respectfully suggests that cancers other than those specified by the Examiner can be treated by these compounds due to general cytotoxic chemotherapeutic action they inflict on tumor DNA.

Accordingly, it is respectfully requested that the section 112 ground for rejection be withdrawn.

**Rejection under 35 U.S.C. §103(a)**

Claims 1-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the WO 97/12630 in view of Ragab U.S. 6,346,524, Burton et al. and Friedman. The Examiner stated that single dosing of temozolomide and irinotecan had been demonstrated by Burton be effective in certain cancer treatments. The Examiner stated that Ragab demonstrated administering an effective amount (40-150 mg/m<sup>2</sup>/day) for a dosing period of from about 5 to 25 days to cure or eliminate cancer. The Examiner stated that Friedman teaches a method of treating cancer (gliomas, melanomas, carcinomas, sarcoma, leukemia, etc.) by use of temozolomide. Col. 10, Lines 35-65. The Examiner stated that Friedman also discloses temozolomide in combination with other chemotherapeutic agents such as irinotecan. Col. 13, lines 1-5.

Applicants respectfully traverse the rejection and state the following.

The mere fact that the prior art could be modified does not make the modification obvious unless the prior art suggests the desirability of the modification. In re Fritch, 23 U.S.P.Q.2d at 1784; In re Laskowski, 10 U.S.P.Q.2d 1397, 1398 (Fed. Cir. 1989); In re Gordon, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984).

"It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed

invention is rendered obvious....'[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'" In re Fritch, 23 U.S.P.Q.2d at 1784 (quoting In re Fine, 5 U.S.P.Q.2d at 1600).

As previously stated by the applicant, because of the differences between the scope of the prior art and the claimed invention, per the first and second Graham factors, applicant respectfully suggests that a prima facie case of obviousness cannot be established. Further, applicant respectfully suggests that impermissible hindsight has been applied with respect to Ragab, Burton and Friedman to establish a case of obviousness.

Applicant claims a method of treatment using therapeutically effective amounts of temozolomide in combination with irinotecan. Therapeutically effective amounts temozolomide and irinotecan are described on pages 4-6 of the specification. Applicant notes that the Examiner concedes that neither reference teaches a combination of temozolomide and irinotecan.

The Examiner notes Ragab and Burton et al. for their disclosure of temozolomide and irinotecan. However, there is no teaching or suggestion in either reference to combine irinotecan in combination with temozolomide to treat cancer.

Burton et al. in fact teaches monotherapy with irinotecan AND temozolomide, but as the Examiner concedes, does not teach a combination therapy of the two compounds. Ragab merely discloses the use of temozolomide **alone**, (see generally, Abstract, col. 2, lines 31-45 and claims 1-11 of Ragab) there is no teaching or suggestion of combination therapy with irinotecan.

The Examiner cites Friedman for the premise that it cites using both temozolomide and irinotecan to treat various cancer. However, Friedman is silent on applicant's amended claim 1, where temozolomide and irinotecan are administered over repeated 21 day cycles, where said 21 day cycles are divided into three 1 week periods. Applicant respectfully suggests that the fact that the three cited references are each silent on a feature of applicant's claim 1 supports a finding of non-obviousness. Applicant respectfully suggests that to render his claimed invention obvious in light of these references, impermissible hindsight must be applied.

Therefore, applicant respectfully submits that the claimed invention is not obvious in light of Friedman, Ragab and Burton et al. Reconsideration and withdrawal of this ground of rejection is respectfully urged.

In view of the remarks above, applicant respectfully submits that the application is in condition for allowance. Accordingly, applicant requests reconsideration of the application, withdrawal of the rejections of record and issuance of a Notice of Allowance.

No fees, other than the appropriate extension of time fees, are due by the submission of this paper however, if any fees are determined to be due by this paper, the Commissioner is hereby authorized to deduct such fees from **Account No. 19-0365**.

The Examiner is requested to call the undersigned attorney on any matter connected with this application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'W. Lee', is written over a horizontal line.

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